UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/786,725	04/23/2001	Hans-Werner Heinrich	101195-44	4120

27387 7590 09/14/2010

LONDA, BRUCE S.
NORRIS MCLAUGHLIN & MARCUS, PA
875 THIRD AVE, 8TH FLOOR
NEW YORK, NY 10022

EXAMINER	
WILLIAMS, KAREN M	

ART UNIT	PAPER NUMBER
PCT	

MAIL DATE	DELIVERY MODE
09/14/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/786,725	HEINRICH ET AL.	
	Examiner	Art Unit	
	JAMES L. GRUN	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 June 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3,6-15 and 17-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,6-15 and 17-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6/25/10*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

The amendment filed 25 June 2010 is acknowledged and has been entered. It is noted again that the new claims filed 02 March 2010 as claims 23 and 23 were renumbered under 37 CFR § 1.126 as claims 23 and 24, respectively, and should be so numbered in future communications. Claims 1, 3, 6-15, and 17-24 remain in the case.

Notwithstanding applicant's assertions to the contrary, no listing of antibodies was found attached to applicant's response filed 25 June 2010.

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification is objected to under 35 U.S.C. § 112, first paragraph, as failing to provide an adequate written description of the invention, and failing to adequately teach how to make and/or use the invention, i.e. failing to provide an enabling disclosure.

Claims 17 and 18 are rejected under 35 U.S.C. 112, first paragraph, for the reasons of record as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, and which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention as is now claimed. As set forth, applicant teaches the immunization of **animals** to obtain specific antibodies for use in diagnostic tests of human elastase and kits therefor. Applicant does not describe or enable any

method or kit in which **the patient** is administered elastase peptides to obtain antibodies. Applicant is again requested to direct the Examiner's attention to specific passages where support for these newly recited limitations can be found in the specification as filed or is required to delete the new matter.

Applicant's arguments filed 25 June 2010 have been fully considered but they are not deemed to be persuasive. Notwithstanding applicant's assertions to the contrary, applicant's amendments have not obviated rejections under this statute for the reasons set forth above.

Claims 1, 3, 6-11, and 17-24 are rejected under 35 U.S.C. 112, first paragraph, for reasons of record, that the specification contains subject matter which was not described in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the **claimed invention**, and which was not described in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use **the invention commensurate in scope with these claims**. For the extensive reasons of record, the issue is whether the disclosure describes and supports the ability of the recited peptides to elicit antibodies that bind **singly**, or in **unguided undefined combination**, and function for determination of elastase isoforms I, II, and/or III in a body fluid sample, not only after SDS denaturation as specifically exemplified.

Applicant's arguments filed 25 June 2010 have been fully considered but they are not deemed to be persuasive. Notwithstanding applicant's assertions to the contrary, applicant's disclosure does not describe and enable the invention as instantly claimed for the extensive reasons of record. Notwithstanding applicant's assertions to the contrary, the showings in the

abstract of Weiss et al. and the other publications provided are not commensurate in scope with the invention as instantly disclosed and/or claimed and/or argued because antibodies produced by the instant assignee (BIOSERV) and used in assays of stool elastase are clearly shown not to bind all isoforms of elastase, the antibodies of undisclosed specificity for the various instantly disclosed peptides bound only to elastase III isoforms. Notwithstanding applicant's assertions to the contrary, the abstract of Keim et al. teaches nothing with regard to the specificity of the antibodies in the BIOSERV kit for multiple isoforms of elastase. Again, a single functional antibody or functional combinations are not clearly disclosed by applicant so that one would know without question what single antibody or combinations predictably functioned in applicant's suggested invention when the application was originally filed.

Notwithstanding applicant's assertions to the contrary, applicant's amendments have not obviated rejections under this statute for the reasons set forth above.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 3, 10, 18, and 20-24 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1 and claims dependent thereupon, the interrelationships of the components and steps of the method are entirely unclear, e.g.: there is no connection between the antibodies raised against peptides and the antibodies obtained by immunizing animals with complete

elastases or subunits in claim 3; there is no connection between the polyclonal antibodies of claim 1 and the monoclonal antibodies of claims 3 or 20; there is no antecedent support in claim 1 as amended for "the . . . peptide administered" in claim 23. In these claims, "using" is not a valid method step. In these claims, "the" content lacks antecedent basis.

In claim 1 and claims dependent thereupon, improper Markush language is used to claim the members of the group. The alternatives "selected from...or" or "selected from the group consisting of...and" are acceptable.

In claim 20, it is believed --myeloma-- was intended.

Claim 21 provides no further limitation of the procedure of claim 1 as amended.

In claim 23, improper Markush language is used to claim the members of the group. The alternatives "selected from...or" or "selected from the group consisting of...and" are acceptable.

Claims 10 and 22 are duplicative, each claiming identical subject matter.

In claim 18, --The-- immunological test kits should be recited for proper reference to the previously recited claim components.

Applicant's arguments filed 25 June 2010 have been fully considered but they are not deemed to be persuasive. Notwithstanding applicant's assertions to the contrary, applicant's amendments have not obviated rejections under this statute for the reasons set forth above.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 6-8, 10, and 22 are rejected under 35 U.S.C. § 102(b) as being anticipated by Sziegoleit et al. (Clin. Biochem. 22: 79, 1989) in light of the instant disclosure for reasons of record.

Claims 6-8, 10, 11, and 22 are rejected under 35 U.S.C. § 102(b) as being anticipated by Scheefers et al. (U.S. Pat. No. 5,622,837) in light of the instant disclosure for reasons of record.

Applicant's arguments filed 25 June 2010 have been fully considered but they are not deemed to be persuasive. Notwithstanding applicant's assertions to the contrary, as set forth in the extensive reasons of record, there is nothing found in the instantly rejected claims that distinguishes the invention as claimed therein from the antibodies and methods taught in the disclosures of the cited references. The instantly rejected claims are not limited to immunization with the peptides as asserted (i.e., as set forth, immunogenic portions can be the whole peptide as comprised in purified enzyme) and are not limited to applicant's argued "antibodies which are the essence of applicant's surprising contribution to the art." As set forth, applicant has provided no *factual* evidence of a difference for the reagents **as instantly claimed** and those as used in the references.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
> (c) Subject matter developed by another person, which qualifies as prior art only under one or more subsections (e), (f) and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103.

Claims 1, 3, 6-15, and 17-24 are rejected under 35 U.S.C. § 103(a) as being unpatentable over the combined teachings of Scheefers et al. (U.S. Pat. No. 5,622,837), Tani et al. (J. Biol. Chem. 263: 1231, 1988), and Harlow et al. for reasons of record in the prior rejection of the similar subject matter of these claims.

Applicant's arguments filed 25 June 2010 have been fully considered but they are not deemed to be persuasive. Applicant presented no arguments, other than to Scheefers et al., alone, relevant to this ground of rejection.

In the previously filed declaration of Dr. Hans-Werner Heinrich and in applicant's arguments it is urged that the antibodies of the prior art are specific for many different epitopes of elastases IIIA and IIIB, bind other enzymes, and are not appropriate for diagnosis. These are not found persuasive for the reasons of record and because applicant has provided no *factual* evidence of a difference for the reagents as instantly claimed and those as used or suggested in the reference. As set forth, Scheefers et al. teach elicitation of both polyclonal and monoclonal antibodies to purified enzyme and fragments thereof, not only to the suggested antigen/immunogen as instantly excluded, for use in sandwich enzyme-linked immunosorbent assay for diagnosis of pancreatic diseases. Moreover, the teaching of a preferred peptide in the reference does not serve to teach away from any other fragment of the enzyme as taught for use in Scheefers et al. (see e.g. col. 2). As set forth, the Patent and Trademark Office does not have the facilities and resources to provide the *factual* evidence needed in order to establish that there

is a difference, in the first place, between the reagents of the prior art and those instantly disclosed and, that if there is such a difference, that such a difference would have been considered unexpected, i.e. unobvious, by one of ordinary skill in the art. The burden is upon applicant to present such factual evidence. See e.g. In re Best (195 USPQ 430 (CCPA 1977)) or Ex parte Phillips (28 USPQ2d 1302 (BPAI 1993)). Applicant's arguments have not met this burden.

Applicant urges that the instant compositions and methods use at least one antibody binding to each of the isoforms. This is not found persuasive because applicant is arguing a limitation not found in the claims. Notwithstanding applicant's allegations to the contrary, recitation of "one or more antibodies" binding peptides, including peptides derived from an elastase isoform not expressed in human pancreas or those from porcine sources, does not indicate that the antibodies of the compositions and methods of the invention include at least one antibody binding each of the isoforms.

Applicant again urges that the claimed invention is already practically used as evidenced by the abstract of Weiss et al. (published variously in: J. Ped. Gastroenterol. Nut.; Pancreatology; and Pancreas) and other publications. This is not found persuasive because the showings in the abstract of Weiss et al. and the other publications are not commensurate in scope with the invention as instantly disclosed and/or claimed and/or argued and teach that applicant was not in possession of the invention as disclosed and/or claimed and/or argued because antibodies produced by the instant assignee (BIOSERV) and used in assays of stool elastase are clearly shown not to bind all isoforms of elastase although elastase II might be expected in the samples.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR § 1.136(a).

A SHORTENED STATUTORY PERIOD FOR REPLY TO THIS FINAL ACTION IS SET TO EXPIRE **THREE MONTHS** FROM THE MAILING DATE OF THIS ACTION. IN THE EVENT A FIRST REPLY IS FILED WITHIN **TWO MONTHS** OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE **THREE-MONTH** SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR REPLY EXPIRE LATER THAN **SIX MONTHS** FROM THE MAILING DATE OF THIS FINAL ACTION.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James L. Grun, Ph.D., whose telephone number is (571) 272-0821. The examiner can normally be reached on weekdays from 11 a.m. to 7 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Shibuya, SPE, can be contacted at (571) 272-0806.

The phone number for official facsimile transmitted communications to TC 1600, Group 1640, is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application, or requests to supply missing elements from Office communications, should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/J. L. G./
James L. Grun, Ph.D.
Examiner, Art Unit 1641
September 13, 2010

/Shafiqul Haq/
Primary Examiner, Art Unit 1641